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No. 90-1583

Supreme Court, U.S.
FILED
JUN 12 1991
OFFICE OF THE CLERK

In the Supreme Court of the United States

OCTOBER TERM, 1990

LEONARD S. DINO, PETITIONER

v.

UNITED STATES OF AMERICA

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE EIGHTH CIRCUIT

BRIEF FOR THE UNITED STATES IN OPPOSITION

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QUESTION PRESENTED

Whether petitioner's convictions for mail fraud and for receiving and distributing adulterated and misbranded drugs were supported by sufficient evidence.

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OPINION BELOW

The opinion of the court of appeals (Pet. App. A36-A43) is reported at 919 F.2d 72.

JURISDICTION

The judgment of the court of appeals was entered on November 14, 1990. A petition for rehearing was denied on February 11, 1991. The petition for a writ of certiorari was filed on April 15, 1991. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

STATEMENT

Following a jury trial in the United States District Court for the Eastern District of Missouri, petitioner was convicted on three counts of mail fraud,

in violation of 18 U.S.C. 1341; one count of receiving and delivering adulterated and misbranded drugs, in violation of 21 U.S.C. 331(c) and 333(b); and one count of conspiracy, in violation of 18 U.S.C. 371. He was sentenced to concurrent 12-month terms of imprisonment on two of the mail fraud counts, with 90 days to be served on work release and the remaining nine months suspended. He was also fined $10,000 on the mail fraud counts. The court suspended imposition of sentence on the remaining counts and placed petitioner on probation for five years. The court of appeals affirmed. Pet. App. A36-A43.

1. The evidence at trial showed that from 1977 until 1986, petitioner was the owner and operator of two pharmacies in the St. Louis, Missouri, area. During that time, he purchased sample prescription drugs from drug company representatives and used those samples to fill his customers' prescriptions. The pharmaceutical samples were often delivered to petitioner out of their original containers, without lot numbers, serial numbers, expiration dates, or "sample" markings. In some instances, the samples had been obtained by the salesmen in violation of company rules. Petitioner typically paid for his supplies by mailing checks directly to the salesmen. Pet. App. A39-A40; Gov't C.A. Br. 4-9.

The samples purchased by petitioner included a prescription cough syrup produced by Carter-Wallace, Inc. After petitioner bought the cough syrup samples, he or his employees typically poured the samples from their individual bottles into larger containers that did not bear either drug lot numbers or expiration dates. The pharmacy filled prescrip-

tions for the cough syrup from the large containers. Pet. App. A40; Gov't C.A. Br. 6.[1]

The director of quality control for Carter-Wallace testified that the bottles in which petitioner stored the cough syrup were designed to hold water-based products and were inappropriate for liquids like the cough syrup. The syrup, he explained, could have caused the bottles to collapse inward as the plastic from which they were made deteriorated. In fact, the bottles that petitioner used to store the cough syrup had begun to collapse in that manner. Although the quality control expert had not performed studies on petitioner's containers, he testified that in his opinion the deterioration of the bottles could cause plastic to leach into and adulterate the cough syrup stored inside. The expert stated that if Carter-Wallace were aware of such contamination, it would recall the entire batch of cough syrup. Pet. App. A17-A24, A43. An expert witness in clinical pharmacy testified that ingestion of plastic-contaminated cough syrup could cause kidney failure, decreased liver function, neurological toxicity, and paralysis. Those effects could also result if expired cough syrup were ingested. Gov't C.A. Br. 13.

2. The court of appeals affirmed. The court ruled that the evidence supported the existence of a fraudulent scheme under 18 U.S.C. 1341, because the jury could conclude that the purchase of inexpensive samples deprived their manufacturers of profits they would have earned had petitioner procured their products legitimately. Furthermore, petitioner's retail sale of samples, which were not intended for resale, denied consumers the benefits of various safety meas-

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[1] The drug samples sold by petitioner also included birth-control pills and "Slow-K." Gov't C.A. Br. 5, 6.

ures such as lot numbers, which are used in case of a recall, and expiration dates, which ensure the drugs' efficacy. The court concluded that petitioner's scheme constituted fraudulent misrepresentation for profit. Pet. App. A39-A43.

The court also held that the drugs petitioner sold were misbranded under 21 U.S.C. 352, which prohibits labeling that is "false or misleading in any particular." Petitioner's drugs were falsely labeled, the court ruled, because they did not have lot numbers or expiration dates. The court explained that "doctors, patients, and drug manufacturers all rely on pharmacists to sell safe and effective drugs—not drugs impossible to trace for a recall, or which may have surpassed an expiration date." Pet. App. A42.

Finally, the court found that petitioner's drugs were adulterated within the meaning of 21 U.S.C. 351, since adulteration includes packaging that is not in conformity with "current good manufacturing practice." Petitioner's storage of the cough syrup in ordinary plastic bottles, and not in the manufacturer's specially designed containers, was not good practice because it jeopardized the purity of the drug. Thus, the drugs were adulterated. Pet. App. A43.[2]

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[2] The court of appeals also rejected petitioner's claims that the evidence failed to prove use of the mails in furtherance of his scheme (Pet. App. A41-A42) and that the district court should have suppressed evidence (*id.* at A43). Petitioner has not raised those contentions in this Court.

ARGUMENT

Petitioner contends that the evidence was insufficient to sustain his conviction. First, he argues (Pet. 6-8) that the mail fraud counts must be reversed under *McNally* v. *United States*, 483 U.S. 350 (1987), because the evidence did not show that the manufacturer or petitioner's customers were defrauded. That argument is without merit.

McNally held that the mail fraud statute is limited to the protection of property rights and does not outlaw schemes to defraud citizens of the intangible right to good government. Thus, in *Carpenter* v. *United States*, 484 U.S. 19 (1987), this Court rejected the argument that a newspaper employee's disclosure of pre-publication information was not proscribed by the mail fraud statute. The Court explained that the mail and wire fraud statutes "reach any scheme to deprive another of money or property," and that the words "to defraud" include "wronging one in his property rights." *Id.* at 27.

In this case, the evidence showed that petitioner devised a scheme to defraud the pharmaceutical manufacturers of money and property. As the court of appeals noted (Pet. App. A41), petitioner bought his drugs from the sales representatives for considerably less than the price charged for the drugs by their manufacturers. The manufacturers were thus deprived of the profits they ordinarily would have made; *i.e.*, they were deprived of money and wronged in their property rights within the meaning of the mail fraud statute.[3] In addition, petitioner's custom-

[3] Petitioner does not argue that he did not deprive manufacturers of their profits, but contends (Pet. 7) that those potential profits were "minuscule." The court of appeals determined, however, that the lost profits were considerable (Pet.

ers were defrauded of basic safeguards when drugs of unkown expiration date and no lot or serial number were substituted for pharmaceuticals that were within their period of efficacy and were subject to recall if the need arose.[4]

Petitioner next argues (Pet. 8-11) that the government failed to prove that the drugs were adulterated or misbranded. He contends that the testimony of the government's expert witness was based upon an insufficient evidentiary foundation and that the evidence of adulteration was therefore inadequate. Because petitioner did not challenge the expert's testimony in the court of appeals (and apparently did not object to the expert's testimony at trial), he has waived that argument. See *Berkemer* v. *McCarty*, 468 U.S. 420, 443 (1984); *United States* v. *Lovasco*, 431 U.S. 783, 788-789 n.7 (1977). In any event, there is no merit to the point.

The government's expert examined the bottles that petitioner used to store the cough syrup and determined that they had begun to collapse inward. The

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App. A41) and in any event the mail fraud statute does not require that a fraud exceed a dollar minimum. Moreover, the record indicates that petitioner paid the drug companies' salesmen for the drugs and not the manufacturers, so the manufacturers apparently obtained no return at all on some of the drugs that petitioner resold. See Gov't C.A. Br. 4-5, 7, 9, 41.

[4] Contrary to petitioner's contention, nothing in the enactment of the Prescription Drug Marketing Act of 1987, Pub. L. No. 100-293, § 4, 102 Stat. 96-98, with its provision restricting the sale of drug samples, 21 U.S.C. 353, absolved petitioner for his fraudulent acts. Schemes in violation of the mail fraud statute are no less criminal because Congress has subsequently addressed the particular fraudulent acts that constituted the scheme.

expert's opinion that the deterioration of the containers could cause toxins to be released into the cough syrup was therefore based on an adequate foundation. Moreover, petitioner's use of containers that were not designed to hold the cough syrup that he stored in them is itself an "adulteration" under the statute, which prohibits packaging a drug in a manner that does not conform with "current good manufacturing practice." 21 U.S.C. 351(a)(2)(B); see Pet. App. A43.

Even if the government's evidence of adulteration was insufficient, the government proved that the drugs were misbranded, which is sufficient to sustain the conviction under 21 U.S.C. 331, since the statute separately prohibits both adulteration and misbranding. The statute defines "misbranded," 21 U.S.C. 352(a), as "false or misleading in any particular," which, as the court of appeals held, includes drugs lacking the safeguards provided by expiration dates and lot numbers. The lot numbers make it possible for the manufacturers to recall defective drugs, and the expiration dates help avoid the risk of injuries of the sort described by the testimony of the clinical pharmacist. Without that information, neither the pharmacist nor the physician can protect the consumer; drugs lacking that information are thus misbranded.[5]

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[5] Petitioner's reliance on *United States* v. *Articles of Drug*, 625 F.2d 665 (5th Cir. 1980), is misplaced. That case held that a doctor's prescription exempts a drug from many of the ordinary labeling requirements because the doctor would convey the necessary safety information to the patient. Nothing in that case leads to the conclusion that pharmaceutical products are properly sold when all evidence of their lot numbers and expiration dates has been erased; indeed, without those data the doctor (as well as the pharmacist and the pa-

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

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JUNE 1991

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tient) could not be sure that a particular lot of a drug was safe and effective.

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